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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/403,844 04/18/95 FODSTAD

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EXAMINER

GABEL, G

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

08/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/403,844

Applicant(s)

FODSTAD ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-25, 28, 29, 33-43, 46-48, 51, 59-62, 64, 66, 67, 69, 71-75 and 78-116 is/are pending in the application.
- 4a) Of the above claim(s) 41-42, 73-74, 80-86, 90-91, 94-95, 97-100, and 102-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-25, 28, 29, 33-40, 43, 46-48, 51, 59-62, 64, 66, 67, 69, 71, 72, 75, 78, 79, 87-89, 92, 93, 96, 101 and 105-116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 22-25, 28-29, 33-43, 46-48, 51, 59-62, 64, 66-67, 69, 71-75, and 78-116 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

DETAILED ACTION

Amendment Entry

1. Applicants' amendment and response filed 4/11/01 in Paper No. 33 is acknowledged and has been entered. Claims 22, 39, 46, 48, 62, 78, 87, and 92 have been amended. Claims 108-116 have been added. Applicants' supplemental amendment and response filed 5/11/01 in Paper No. 34 is also acknowledged and has been entered. Claim 48 has been further amended.

Currently, claims 22-25, 28-29, 33-40, 43, 46-48, 51, 59-62, 64, 66-67, 69, 71-72, 75, 78-79, 87-89, 92-93, 96, 101, and 105-116 are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 103

2. In light of Applicant's amendment, the rejection of claims 22-25, 28-29, 33, 37-38, 46-48, 51, 59-62, 64, 69, 78-79, 101, and 105-107 under 35 U.S.C. 103(a) as being unpatentable over Widder et al. (EP 016,552) in view of Connelly et al. (US 5,422,277) is hereby, withdrawn.

3. In light of Applicant's amendment, the rejection of claims 22, 34-36, 39, 40, 43, 48, 66, 67, 71, 72, 75, 87-89, 92, 93, and 96 under 35 U.S.C. 103(a) as being unpatentable over Widder et al. (EP 016,552) and Connelly et al. (US 5,422,277) in view of Kemmer et al. (Journal of Immunological Methods, 1992) and Holmes et al. (WO 91/09938) is hereby, withdrawn.

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4. In light of Applicant's amendment, the rejection of claims 22-25, 28-29, 33-40, 43, 46-48, 51, 59-62, 64, 66-67, 69, 71-72, 75, 78-79, 87-89, 92-93, 96, 101, and 105-107 under 35 U.S.C. 103(a) as being unpatentable over Jensen (US 5,374,531) taken altogether with Hermentin et al. (US 5,095,097) or Ullman et al. (US 5,536,644) is hereby, withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 22-25, 28-29, 33-40, 43, 46-48, 51, 59-62, 64, 66-67, 69, 71-72, 75, 78-79, 87-89, 92-93, 96, 101, and 105-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22, as amended, remains incomplete for omitting essential elements and method steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 22, step (f) recites "visually detecting ... target cell/bead rosettes" but it is unclear how target cell/bead rosettes can be detected in the absence of a label, i.e. enzyme label for use in immunohistochemical staining. Claim 22 appears to be drawn to a method of detecting a specific target cell in cell suspensions but elements are lacking so as to effect a "visual detection" capability.

Claim 22, in step a) has improper antecedent basis problem in reciting "the second antibody".

Claim 22, in step b) lacks antecedent support in reciting "the cell mixture", first and second occurrence. Perhaps Applicant intends to refer back to the "cell suspension" in the preamble since the cell suspension in the preamble has not been incubated with the second antibody. Applicant appears to intend to refer to the "cell mixture" as the mixture (created) after the cell suspension and the second antibody is incubated. (See subsequent step c) for reference).

Claim 22 in step b) lacks clear antecedent support in reciting "to bind **the** antibody" because it is unclear which antibody (first or second) is being referred back to in the claim.

Claim 46 is indefinite in reciting "capable of coating" because it fails to recite a positive limitation in the claim. Further, the specificities of the claimed first and second antibodies in the kit of claim 46 do not appear to be consistent (for use) with the first and second antibodies in method claim 22 from which it depends.

Claim 48, as amended, remains incomplete for omitting essential elements and method steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 48, step (f) recites "visually detecting ... target cell/bead rosettes" but it is unclear how target cell/bead rosettes can be detected in the absence of a label, i.e. enzyme label for use in immunohistochemical staining. Claim 48 appears to be drawn to a method of detecting a specific target cell in a cell suspension but elements are lacking so as to effect a "visual detection" capability.

Claim 48, in step b) lacks antecedent support in reciting "the cell mixture", first and second occurrence. Perhaps Applicant intends to refer back to the "cell suspension" in the preamble since the cell suspension in the preamble has not been incubated with the second antibody. Applicant appears to intend to refer to the "cell mixture" as the mixture (created) after the cell suspension and the second antibody is incubated. (See subsequent step c) for reference).

Claim 48 in step b) lacks clear antecedent support in reciting "to bind **the** antibody" because it is unclear which antibody (first or second) is being referred back to in the claim.

The term "low" in claim 62 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "high" in claim 71 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 78 is incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. It is unclear what structural cooperative relationship exists between the first monoclonal antibody, second monoclonal antibody, and labeled third monoclonal antibody in claim 78 so as to enable use of the claimed kit

for the method in claims 22 and 111 from which it depends since claims 22 and 111 do not appear to have a recitation of "a labeled third antibody". Further, the specificities of the claimed first and second antibodies in the kit do not appear to be consistent with the first and second antibodies in the claimed method.

Claim 87, as amended, remains incomplete for omitting essential elements and method steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 87, step (f) recites "visually detecting ... target cell/bead rosettes" but it is unclear how target cell/bead rosettes can be detected in the absence of a label, i.e. enzyme label for use in immunohistochemical staining. Claim 87 appears to be drawn to a method of detecting a specific target cell in a cell suspension but elements are lacking so as to effect a "visual detection" step.

In claim 87, step f), insert "rosettes" after "tumor cell-bead" for clarity.

Claim 92, as amended, remains incomplete for omitting essential elements and method steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 92, step (f) recites "visually detecting ... target cell/bead rosettes" but it is unclear how target cell/bead rosettes can be detected in the absence of a label, i.e. enzyme label for use in immunohistochemical staining. Claim 92 appears to be drawn to a method of detecting a specific target cell in a cell suspension but elements are lacking so as to effect a "visual detection" step.

Claim Rejections - 35 USC § 103

6. Claims 46-47, 78-79, 106, and 107 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Widder et al. (EP 016,552) and Connelly et al. (US 5,422,277) in view of Forrest et al. (U.S. Patent 4,659,678) for reason of record.

New Ground of Rejection

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 110, 114, and 116 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In this case, the specification does not appear to provide any literal support for the recitation of "the target cells are detected at a sensitivity of one target cell per 100 or more total cells". Furthermore, none of the originally filed claims recited the limitation in question. Recitation of claim limitation lacking literal support in the specification or originally filed claims constitutes new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 22-25, 28-29, 33, 37-38, 51, 59-62, 64, 69, 101, 105, and 108-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Widder et al. (EP 016,552) in view of Connelly et al. (US 5,422,277) and in further view of Abram et al. (US 4,497,900).

Widder et al. teach a method for separation of select population of cells from a mixed cell population using magnetic particles coated with a layer of specific antibodies which selectively bind to the select population. The coated microspheres with antibodies specific to target cells are contacted with the mixed population and the bound select population is magnetically separated from the mixed population (see page 4, last paragraph). The magnetically responsive microspheres have Protein A associated into the surface which selectively binds antibodies through the Fc region of the antibodies so that Fab arms of the antibodies extend outwardly for binding (see page 4, first

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paragraph). Widder et al. teach microspheres which are coupled with FITC conjugated rabbit IgG by incubation at 37°C for 20 minutes and examined (see page 10, Example 1). Furthermore, Widder et al. teach using the coated particles to separate red blood cells (RBC) from suspensions containing a mixture of different RBCs. Antibodies were coupled to the microspheres by incubation of 0.5 mg of the microspheres suspended in 0.2 ml. of 0.9% NaCl solution containing 0.1% Tween 80 (polyethylene sorbitans monooleate). The RBCs were labeled with ⁵¹Cr and incubated with mild agitation and bound microspheres were separated and counted using a gamma counter (see page 11, Example 2).

The method of Widder et al differs from the instant invention in failing to teach incubation of the antibody coated microspheres in mild detergent for 5-10 minutes to 2 hours at 4°C. Furthermore, Widder fails to teach the use of an antibody to immobilize antibodies on the surface of the magnetic particles.

Connelly et al. teach various fixatives used to fix cells without destroying cellular properties. Connelly et al. specifically teach fixing cells with phosphate buffer solution followed by DMSO and DNBS, TweenTM (polyethylene sorbitans monolaurate - Tween 20 or monooleate - Tween 80) and formaldehyde (see column 9, lines 10-14) and then incubating the cells for 20 minutes to 2 hours at temperatures ranging from 0°C to 37°C (see column 9, lines 20-48).

It would have been obvious to one of ordinary skill in the art to use detergents to treat cells as used by Connelly following certain specific temperature and time parameters because the use detergents to treat cells is well known and conventional in

the art for removing extraneous matter from the cells that will interfere with assays. One of ordinary skill in the art would have been motivated to incorporate Connelly's fixative techniques and parameters in Widder separation method because Connelly specifically states that one of ordinary skill in the art of cell fixation may routinely have to vary the aforementioned cell treatment parameters as in Widder's RBCs (dependent on cellular type) in order to obtain desired cell fixation without substantial destruction of cellular properties.

Widder et al. and Connelly et al. fail to teach that the first antibody is directed against a second antibody or antibody fragment that is directed against a cell membrane structure.

Abram et al. disclose an immunoassay for determining the presence of antigen wherein antigen-antibody complexes comprising antigen and secondary antibody are further incubated (treated) with primary antibody (antiglobulin). Specifically, the primary antibody is directed against the secondary antibody that is bound to the antigen.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use antibodies directed to other antibodies such as taught by Abram to immobilize other antibodies on the surface of the magnetic particles in the method of Widder and Connelly because Abram specifically taught that a primary antibody directed against a secondary antibody can be used for binding two elements to form complexes, such as a label to an antigen (label -1^o antibody- 2^o antibody – analyte complexes) or a paramagnetic bead to a cell surface antigen (paramagnetic bead – 1^o antibody – 2^o antibody – cell surface antigen complexes) and Widder specifically taught

that immobilizing specific antibodies on a surface of a solid support, such as magnetic particles is conventional and well known in the art.

9. Claims 22, 46-48, 78-79, 106, 107, and 112-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Widder et al. and Connelly et al. (US 5,422,277) in view of Forrest et al. (U.S. Patent 4,659,678) and in further view of Abram et al. (US 4,497,900).

Widder et al. and Connelly et al. have been discussed supra. The methods of Widder et al. and Connelly et al. differ from the instant invention in failing to teach the use avidin-biotin system and a test kit.

Forrest et al teach a sandwich assay wherein a complex is formed between antigen in a sample and two or more antibody reagents and bound to solid supports such as magnetic or paramagnetic particles or beads having labeled or unlabeled antibodies attached thereto (see Abstract, column 1 and 2). The label employed may be selected from those known in the art such as fluorimetric or enzyme labeling. Forrest et al. teach using Protein A attached to the solid support and further attached to an antibody (see column 3-4). Forrest et al. teach using antibody reagents (which constitute intact antibodies or fragments thereof) that constitute a specific binding protein such as avidin and biotin and adding the reagents in any order so as to optimize the reaction conditions (column 5).

It would have been obvious to one of ordinary skill in the art to use a binding system such as avidin-biotin as taught by Forrest et al. in the methods of Widder et al.

and Connelly et al. because Forrest et al. teach that avidin-biotin provides a very rapid and high binding affinity which offers the advantage of a more accurate and rapid assay. It would also have been obvious to one of ordinary skill in the art at the time of the instant invention to use a binding system used by Forrest et al. in the methods of Widder et al. and Connelly et al., as modified by Forrest et al in a test kit arrangement because test kits are conventional and well known in the art for their recognized advantages of convenience and economy.

Widder et al., Connelly et al., and Forrest et al. fail to teach that the first antibody is directed against a second antibody or antibody fragment that is directed against a cell membrane structure.

Abram et al. has been discussed supra. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate antibodies directed to other antibodies such as taught by Abram for immobilizing other antibodies on the surface of magnetic particles into a system or kit format such as taught by Widder, Connelly, and Forrest combined because Abram specifically taught that a primary antibody directed against a secondary antibody can be used for binding two elements to form complexes, such as a label to an antigen (label -1° antibody- 2° antibody – analyte complexes) or a paramagnetic bead to a cell surface antigen (paramagnetic bead – 1° antibody – 2° antibody – cell surface antigen complexes) and Widder specifically taught that immobilizing specific antibodies on a surface of a solid support, such as magnetic particles is conventional and well known in the art.

10. Claims 22, 34-36, 39, 40, 43, 48, 66, 67, 71, 72, 75, 87-89, 92, 93, 96, and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Widder et al. (EP 016,552) and Connelly et al. (US 5,422,277) in view of Kemmer et al. (Journal of Immunological Methods, 1992) and Holmes et al. (WO 91/09938) and in further view of Abram et al. (US 4,497,900).

Widder et al. and Connelly et al. have been discussed supra. The methods of Widder et al. and Connelly et al. differ from the instant invention in failing to teach separation and detection of specific cells, in this case, cancer cells.

Kemmer et al. teach isolation of tumor cells from a mixed cell suspension of human tumor tissue which contains tumor cells, leucocytes, and erythrocytes, using magnetic beads coated with monoclonal antibodies.

Holmes et al. teach a method of separating hematopoietic progenitor cells from a mixed population of hematopoietic cells which contain malignant cells using microbeads coated with murine antibody which binds to the Fc portion of IgG murine antibodies or Protein A which reacts universally with the Fc portion of virtually all IgG antibodies (see page 6, lines 8-24). The mixed population of Holmes et al. is commonly derived from the bone marrow mononuclear cells, fetal, and umbilical cord blood or adult human blood.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the method of cell separation taught by Widder, as modified by Connelly, to separate cells from a variety of cell samples as taught by Kemmer and Holmes because Kemmer and Holmes teach that it is advantageous to remove tumor

cells from a mixed population using magnetic microbeads coated with either monoclonal antibodies or protein A for the purpose of further studying the tumor cells or to purge a sample of tumor cells. The use of various monoclonal antibodies specific for antigens present on the cell surface for binding, separation, and detection is well known in the art and a skilled artisan would have had a reasonable expectation of success in choosing an antibody that is specific for an antigen present on the surface if the cell population of interest.

Widder et al., Connelly et al., Kemmer et al., and Holmes et al. fail to teach that the first antibody is directed against a second antibody or antibody fragment that is directed against a cell membrane structure.

Abram et al. has been discussed supra. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate antibodies directed to other antibodies such as taught by Abram for immobilizing other antibodies on the surface of magnetic particles into a method such as taught by Widder, Connelly, Kemmer, and Holmes combined because Abram specifically taught that a primary antibody directed against a secondary antibody can be used for binding two elements to form complexes, such as a label to an antigen (label -1° antibody- 2° antibody – analyte complexes) or a paramagnetic bead to a cell surface antigen (paramagnetic bead – 1° antibody – 2° antibody – cell surface antigen complexes) and Widder specifically taught that immobilizing specific antibodies on a surface of a solid support, such as magnetic particles is conventional and well known in the art.

Response to Arguments

11. a) Applicant argues that the claimed invention, including claims 46-47, 78-79, 106, and 107, provides a method and kit for detecting target cells where antibodies that recognize cell membrane structures are not directly bound to the paramagnetic particles. Instead the paramagnetic particles are coated with antibodies which are directed against primary antibodies that recognize cell membrane structures in target cells wherein the primary antibodies are first incubated with the cell suspension containing the target cells and washed prior to contacting with the coated paramagnetic particles.

In response, the combination of Widder, Connelly, and Forrest disclose magnetic particles which have protein A in the surface onto which a layer of antibodies are coated and the antibodies selectively bind to a target population of cells. Protein A selectively binds antibodies through the Fc region of the antibodies so that Fab arms of the antibodies extend outwardly for binding. Such disclosure of these three references as combined reads on claims 46-47, 78-79, and 106-107 as currently recited. Claims 46-47, 78-79, and 106-107, therefore, remain obvious over the combination of Widder, Connelly, and Forrest.

Further, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. paramagnetic particles are coated with antibodies which are directed against primary antibodies that recognize cell membrane structures in target cells wherein the primary antibodies are first incubated with the cell suspension

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containing the target cells and washed prior to contacting with the coated paramagnetic particles) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

12. Applicant's arguments with respect to claims 22-25, 28-29, 33-40, 43, 46-48, 51, 59-62, 64, 66-67, 69, 71-72, 75, 78-79, 87-89, 92-93, 96, 101, and 105-107 have been considered but are moot in view of the new grounds of rejection. Accordingly, no claims are allowed.

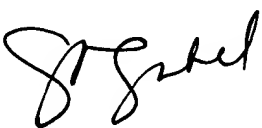
13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

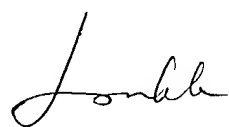
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 308-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gailene R. Gabel
Patent Examiner
Art Unit 1641


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

08/13/01